

I. Rejection under 35 U.S.C. § 112, first paragraph

Claims 4 and 14 were rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly does not enable the use of any HMG-1 or HMG-2 family protein.

Claims 4 and 14 have been amended using language suggested by the Examiner in the Final Office Action. Applicant respectfully requests that the rejections of claims 4 and 14 under 35 U.S.C. § 112, first paragraph be withdrawn.

II. Rejection under 35 U.S.C. § 112, second paragraph

Claims 6 and 16 were rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite in claiming the subject matter of the invention.

The Examiner asked for clarification regarding whether or not chicken and mouse HMG-1 and HMG-2 proteins have 90% and 80% sequence homology, respectively. Claims 6 and 16 have been amended to reflect that A) the polypeptide having an amino acid sequence homology of 90% or more with SEQ ID NO:1 is chosen from human, bovine, porcine, chicken, mouse, or rat HMG-1; and B) the polypeptide having an amino acid sequence homology of 80% or more with SEQ ID NO:2 is chosen from human, bovine, porcine, chicken, mouse, or rat HMG-2.

Furthermore, attached as Exhibit A are amino acid sequence comparisons demonstrating that the chicken and mouse HMG-1 proteins have at least 90% sequence homology with the human HMG-1 protein, and that the chicken and mouse HMG-2 proteins have at least 80% sequence homology with the human HMG-2 protein.

The BLAST program from the National Center for Biotechnology Information (<http://www.ncbi.nih.gov>) was used for the sequence alignments. The “gi” number for the sequences are as follows:

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gi 4140289	chicken HMG-1
gi 123369	human HMG-1
gi 123373	chicken HMG-2
gi 123374	human HMG-2

The amino acid sequences of human HMG-1, chicken HMG-2, and human HMG-2 are disclosed in the instant application. The amino acid sequence of chicken HMG-1 is disclosed in, for example, *Gene* 225(1-2): 97-105, 1998 (see Exhibit B).

The sequence alignment shown in Exhibit A. As indicated in the middle of Exhibit A, page 1, the amino acid sequence homology between chicken HMG-1 human HMG-1 is 90% ($195/215 = 90.7\%$). Furthermore, as shown in the middle of Exhibit A, page 2, the amino acid sequence homology between chicken HMG-2 human HMG-2 is 90% ($188/207 = 90.8\%$).

Table 1 of *Nucleic Acids Research* 20(13): 3516, 1992 (Exhibit C) indicates a sequence homology (identity) of 99.1% between mouse HMG-1 protein and human HMG-1 protein. Table 2 of *Nucleic Acids Research* 20(18): 4927, 1992 (Exhibit D) indicates a sequence homology of 85% between mouse HMG-2 protein and human HMG-2 protein.

Applicant asserts that claims 6 and 16 are clear and definite. Applicant respectfully requests that the rejections of claims 6 and 16 under 35 U.S.C. § 112, second paragraph be withdrawn.

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant respectfully submits that no amendments have been made to the pending claims for the purpose of overcoming any prior art

Serial No. 09/214,881
Response to Final Office Action Dated April 8, 2002

rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



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Marked up version of rewritten claims amended in this Response

4. (Four Times Amended) A kit for diagnosing an autoimmune disease, the kit comprising:
a first antigen [comprising a human HMG-1 polypeptide,] selected from the group consisting of a polypeptide having an amino acid sequence homology of 90% or more with [human HMG-1 indicated by] SEQ ID NO:1, [or] and a fragment [thereof which reacts] of said polypeptide, wherein said polypeptide or fragment thereof specifically binds with an antibody from an autoimmune disease patient;
a second antigen [comprising a human HMG-2 polypeptide,] selected from the group consisting of a polypeptide having an amino acid sequence homology of 80% or more with [human HMG-2 indicated by] SEQ ID NO:2, [or] and a fragment [thereof which reacts] of said polypeptide, wherein said polypeptide or fragment thereof specifically binds with an antibody from an autoimmune disease patient;
a first component for detecting a first antigen-antibody complex; and
a second component for detecting a second antigen-antibody complex; wherein the autoimmune disease is selected from the group consisting of rheumatoid arthritis, human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, primary biliary cirrhosis, microscopic polyangiitis/polyarteritis nodosa, ulcerative colitis, Crohn's disease and autoimmune hepatitis.
6. (Twice Amended) The kit of claim 4, wherein:
the polypeptide [from an HMG-1 family] having an amino acid sequence homology of 90% or more with SEQ ID NO:1 is selected from human, bovine, porcine, chicken, mouse, or rat HMG-1; and
the polypeptide [from an HMG-2 family] having an amino acid sequence homology of 90% or more with SEQ ID NO:2 is selected from human, bovine, porcine, chicken, mouse, or rat HMG-2.
14. (Twice Amended) A diagnostic drug for detecting an antibody of autoimmune diseases, wherein: the drug comprises:
[a human HMG-1 polypeptide,] a polypeptide having an amino acid sequence homology of 90% or more with [human HMG-1 indicated by] SEQ ID NO:1, or a fragment [thereof which reacts] of said polypeptide, wherein said polypeptide or fragment .

thereof specifically binds with an antibody from an autoimmune disease patient;
or

[a human HMG-2 polypeptide,] a polypeptide having an amino acid sequence homology of 80% or more with [human HMG-2 indicated by] SEQ ID NO:2, or a fragment [thereof which reacts] of said polypeptide, wherein said polypeptide or fragment thereof specifically binds with an antibody from an autoimmune disease patient;
[the drug reacts with an antibody of an autoimmune disease patient;] and
wherein the autoimmune disease is selected from the group consisting of rheumatoid arthritis, human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, primary biliary cirrhosis, microscopic polyangiitis/polyarteritis nodosa, ulcerative colitis, Crohn's disease and autoimmune hepatitis.

16. (Amended) The diagnostic drug of claim 14, wherein:
the polypeptide having an amino acid sequence homology of 90% or more with SEQ ID NO:1 is human HMG-1, [human HMG-2,] bovine HMG-1, [bovine HMG-2,] porcine HMG-1, [porcine HMG-2,] chicken HMG-1, [chicken HMG-2,] mouse HMG-1, [mouse HMG-2,] or rat HMG-1[, or rat HMG-2]; and
the polypeptide having an amino acid sequence homology of 80% or more with SEQ ID NO:2 is human HMG-2, bovine HMG-2, porcine HMG-2, chicken HMG-2, mouse HMG-2, or rat HMG-2.